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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,538	03/07/2002	Deb K. Chatterjee	0942.5250001	8240

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EXAMINER	
PROUTY, REBECCA E	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/091,538	CHATTERJEE ET AL.	
	Examiner	Art Unit	
	Rebecca E. Prouty	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-54* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 8-17, 21, 22, 27, 29, 30, 34, 37, 39-42, and 51-54, drawn to an *in vitro* synthesis system comprising a cell extract with reduced nuclease activity, classified in class 435, subclass 194.

II. Claims 1, 3, 16-18, 21, 22, 34, 37, 39-42, and 51-54, drawn to an *in vitro* synthesis system comprising a cell extract with reduced phosphatase activity, classified in class 435, subclass 194.

III. Claims 1, 4, 16, 17, 34, 37, 39-42, and 51-54, drawn to an *in vitro* synthesis system comprising a cell extract with reduced polymerase activity, classified in class 435, subclass 194.

IV. Claims 1, 5, 16, 17, 27-30, 35, 38-42, and 51-54, drawn to an *in vitro* synthesis system comprising a nuclease inhibitor, classified in class 435, subclass 184.

V. Claims 1, 6, 16, 17, 35, 38-42, and 51-54, drawn to an *in vitro* synthesis system comprising a phosphatase inhibitor, classified in class 435, subclass 184.

VI. Claims 1, 7, 16, 17, 35, 38-42, and 51-54, drawn to an *in vitro* synthesis system comprising a polymerase inhibitor, classified in class 435, subclass 184.

VII. Claims 1, 16, 17, 19, 20, 23-26, 31-33, 36, 39-41, and 51-54, drawn to an *in vitro* synthesis system comprising at least two energy sources, classified in class 435, subclass 194.

VIII. Claims 43, 44 and 48, drawn to methods of producing protein or nucleic acids using an *in vitro* synthesis system comprising a cell extract with reduced nuclease activity, classified in class 435, subclass 68.1 or 91.5.

IX. Claims 43, 44, and 48, drawn to methods of producing protein or nucleic acids using an *in vitro* synthesis system comprising a cell extract with reduced phosphatase activity, classified in class 435, subclass 68.1 or 91.5.

X. Claims 43 and 48, drawn to methods of producing protein or nucleic acids using an *in vitro* synthesis system comprising a cell extract with reduced polymerase activity, classified in class 435, subclass 68.1 or 91.5.

XI. Claims 43, 45 and 48, drawn to methods of producing protein or nucleic acids using an *in vitro* synthesis system comprising a nuclease inhibitor, classified in class 435, subclass 68.1 or 91.5.

XII. Claims 43 and 48, drawn to methods of producing protein or nucleic acids using an *in vitro* synthesis system comprising a phosphatase inhibitor, classified in class 435, subclass 68.1 or 91.5.

XIII. Claims 43 and 48, drawn to methods of producing protein or nucleic acids using an *in vitro* synthesis system comprising a polymerase inhibitor, classified in class 435, subclass 68.1 or 91.5.

XIV. Claims 43, 46, and 47, drawn to methods of producing protein or nucleic acids using an *in vitro* synthesis system comprising at least two energy sources, classified in class 435, subclass 68.1 or 91.5.

XV. Claims 49 and 50, drawn to methods of constructing an *in vitro* synthesis system comprising a nuclease inhibitor, classified in class 435, subclass 184.

XVI. Claims 49 and 50, drawn to methods of constructing an *in vitro* synthesis system comprising a phosphatase inhibitor, classified in class 435, subclass 184.

XVII. Claims 49 and 50, drawn to methods of constructing an *in vitro* synthesis system comprising a polymerase inhibitor, classified in class 435, subclass 184.

XVIII. Claim 49, drawn to methods of constructing an *in vitro* synthesis system comprising at least two energy sources, classified in class 435, subclass 184.

The inventions are distinct, each from the other because of the following reasons:

Groups I-VII are distinct as each of the *in vitro* synthesis systems comprise different components and thus have different effects. As the methods of Groups VIII-XIV are each methods of use of these distinct systems and the methods of Groups XV-XVIII are methods of making the systems of Groups IV-VII, Groups VIII-XIV or XV-XVIII are distinct for the same reasons.

Inventions I and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process of making proteins or nucleic acids can be practiced with an unmodified

wheat germ or rabbit reticulocyte extract. Inventions II and IX, III and X, IV and XI, V and XII, VI and XIII or VII and XIV are similarly related and distinct for the same reasons.

Inventions XV and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed could be produced by making a cell extract of a cell transformed with a DNA encoding a nuclease inhibitor protein.

Inventions XVI and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed could be produced by making a cell extract of a cell transformed with a DNA encoding a phosphatase inhibitor protein.

Inventions XVII and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed could be produced by making a cell extract of a cell transformed with a DNA encoding a polymerase inhibitor protein.

Inventions XVIII and VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed could be produced by making a cell extract of a cell transformed with genes encoding the biosynthesis of PEP and carbamoyl phosphate.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter as shown by their

different classification, restriction for examination purposes as indicated is proper.

Group I contains claims directed to the following patentably distinct species of nuclease whose activity is reduced in the cell extract: DNA exonuclease, DNA endonuclease A, RNase exonuclease, RNase E, OmpT, endonuclease I, RNase I, RNase I*, and RecBCD. Each of these nucleases are distinct as they each have chemically different structures, which are encoded by distinct genes.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 2, 8, 12, 21, 22, 29, 30, 34, 37, 39-42, and 51-54 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the**

patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product

claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (571) 272-0937. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Rebecca Prouty
Primary Examiner
Art Unit 1652